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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,343	10/11/2000	Pierre Charneau	03495.0197	4371
22852	7590	02/26/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			ANGELL, JON E	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

197

Office Action Summary	Application No. 09/685,343	Applicant(s) CHARNEAU ET AL.	
	Examiner J. Eric Angell	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-55 and 57-79 is/are rejected.
- 7) ☒ Claim(s) 56 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Action is in response to the communication filed on 11/25/03. The amendment has been entered. All previous claims have been cancelled. New claims 53-79 are currently pending in the application and are examined herein.

2. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections, as they would pertain to the instant claims, which are not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 53-55, 57-74 and 76-79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. The instant claims are drawn to an isolated or purified nucleic acid comprising a retroviral nucleic acid sequences including (1) packaging sequences, (2) cis-acting sequences for reverse transcription, (3) cis-acting sequences for virus integration, (4) at least one cPPT sequence and at least one CTS sequence, wherein any other sequence of pol, other than the

Art Unit: 1635

178 bp fragment comprising the cPPT and CTS sequence is absent, and (5) optionally a cis-acting sequence RRE (e.g., see claim 53); as well as methods of using the nucleic acid.

The claims now encompass a nucleic acid which comprises at least one cPPT sequence and at least one CTS sequence, but no sequence of *pol* outside the 178bp fragment that comprises cPPT and CTS. It is respectfully that the claims negative limitation “wherein any other sequence of *pol*, other than the 178 bp fragment comprising the cPPT and CTS sequence is absent” does not limit the claim such that the nucleic acid must comprise the 178 bp fragment comprising cPPT and CTS. The negative limitation merely limits the claim from having anything outside of the 178bp fragment described in the specification. Therefore, the claims encompass a nucleic acid comprising at least one cPPT sequence and at least one CTS sequence wherein there is no other sequence of *pol* present, other than the cPPT sequence and the CTS sequence. As indicated in the previous Office Action, the specification does not provide explicit support for a nucleic acid comprising only the cPPT and CTS sequences of *pol* and no other sequence of *pol*. Additionally, the specification does not have implicit basis for a nucleic acid comprising at least one cPPT sequence and at least one CTS sequence wherein there is no other sequence of *pol* present, because the specification only discloses a 178 bp fragment of *pol* comprising a cPPT sequence and a CTS sequence. Specifically, the specification indicates,

“A 178 bp fragment of pLAI3 (4793 to 4971), **encompassing cPPT and CTS**, was amplified by PCR. *NarI* restriction sites were added in 5’ of the primers with the aim of inserting this fragment into the unique *ClaI* site of HR GFP...” (Emphasis added, See p. 31, lines 9-12).

This statement clearly indicates that a 178 bp PCR fragment comprising both the cPPT sequence and the CTS sequence, as well as the intervening *pol* sequence is present in the vector.

Art Unit: 1635

Therefore, the specification does not provided basis for a nucleic acid having at least one cPPT sequence and at least on CTS sequence **wherein any other sequences of *pol* is absent.**

Furthermore, there does not appear to be support anywhere in the specification for a sequence that comprises anything less than the 178 bp fragment comprising a cPPT and CTS, as described.

It is noted that the claims can be amended to positively reflect that the nucleic acid comprises the 178bp fragment comprising the cPPT and CTS sequence and no other *pol* sequence. For instance, amending part (4) of claim 53 (and similarly amending claims 65, 71, 76, 78 and 79) to recite “the 178 bp fragment comprising the cPPT sequence and the CTS sequence, wherein any other sequence of *pol* other than said 178 bp fragment, is absent” would obviate this rejection.

6. Additionally, claims 53-55, 57-74 and 76-79 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Specifically, the claims encompass a nucleic acid having less than the 178bp fragment which contains the cPPT and CTS sequences. The specification indicates that the 178bp fragment comprising the cPPT and CTS sequence is critical or essential to the practice of the invention. Since this critical or essential element is not included in the claim(s), the claims are not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

7. As indicated above, the claims are drawn to a nucleic acid (and methods of using said nucleic acid) wherein the nucleic acid comprises at least one cPPT sequence and at least on CTS sequence wherein any other sequences of *pol* is absent. The specification indicates that the

Art Unit: 1635

178bp fragment that comprises the cPPT and CTS sequences is required for the Triplex-forming functions of the nucleic acid. This is demonstrated by the experiments which show that when the 178bp region is absent the nucleic acid does not function as desired. Furthermore, there is no disclosure indicating that anything less than the 178bp fragment can confer the desired function (the ability to form triplex structures) to a nucleic acid sequence. Therefore, based on the disclosure provided in the specification the 178bp fragment is considered to be a critical and essential element that must be explicitly present in the claim(s) in order for the claim to be enabled.

It is noted that the claims can be amended to positively reflect that the nucleic acid comprises the 178bp fragment comprising the cPPT and CTS sequence and no other *pol* sequence. For instance, amending part (4) of claim 53 (and similarly amending claims 65, 71, 76, 78 and 79) to recite "the 178 bp fragment comprising the cPPT sequence and the CTS sequence, wherein any other sequence of *pol* other than said 178 bp fragment, is absent" would obviate this rejection.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 75 is rejected under 35 U.S.C. 102(b) as being anticipated by Zufferey (Nature Biotech. 1997, IDS Ref. No. 4).

Claim 75 is drawn to a nucleic acid comprising the ClaI insert and EcoRI-BamHI insert of pTRIPAU3EF1 α GFP. It is respectfully pointed out that the claim is broad, and therefore encompasses any nucleic acid comprising said inserts. Based on the disclosure in the specification it appears that the nucleic acid of the claimed inserts comprises a sequence having the CMV promoter sequence, as well as the cPPT and CTS sequences. Zufferey teaches an HIV-1 based vector having a nucleic acid comprising the CMV promoter and pol sequence, which comprises cPPT and CTS sequences (e.g., see Fig. 3, p. 873). Specifically, Zufferey teaches, an HIV-I based vector in which the expression cassette for the transgene is flanked by the HIV-I-derived cis-acting sequences necessary for packaging, reverse transcription and integration" (see p. 871, last paragraph). Zufferey indicates that the transgene of the vector can be a reporter gene, such as Luciferase or lacZ (e.g., see p. 873, Table 1, Table 2). Zufferey teaches methods of using the vector to deliver the transgene into cells where it is expressed (indicating delivery to the nucleus) as well as assays which encompass isolating the reporter gene and assaying for its presence/activity (e.g., see Tables 1, 2). Therefore, Zufferey teaches the claims nucleic acid.

Claim Objections

10. Claim 56 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

11. Applicant's arguments filed 11/25/03 have been fully considered.

Art Unit: 1635

12. Applicants' arguments with respect to the objection of claims are persuasive, with the exception of the objection to claim 56. Claim 56 is objected to for the reasons set forth herein.

13. Applicants' arguments with respect to the rejection of claims under 35 USC 112, first paragraph are persuasive for the rejections of the previous claims, however, the new claims are rejected under 35 USC 112, first paragraph for the reasons set forth herein.

14. Applicants' arguments with respect to the rejection of claims under 35 USC 102, as they pertain to the previous claims are persuasive, with the exception of the rejection of claim 75, which is rejected for the reasons set forth herein.

15. With respect to the new claims, Applicants argue that the claims have been amended per the Examiner's recommendation in the previous Office Action, and therefore, the rejections should be withdrawn.

In response, it is respectfully pointed out that the Examiner indicated in the previous Office Action "the claims can be amended to reflect that the nucleic acid comprises the 178bp fragment comprising the cPPT and CTS sequence and no other *pol* sequence" (e.g., see p. 6 of the previous Office Action). The new (amended) claims do overcome the claim objections (except claim 56) and the rejection of claims under 35 USC 102 (except claim 75) because the claims have been amended such that the claims cannot encompass any sequence of *pol* outside the 178bp fragment described. However, the new claims have not been specifically limited to a nucleic acid that explicitly comprises the 178bp fragment, including the cPPT sequence, the CTS sequence, and the sequence between the cPPT and CTS sequences. Therefore, as indicated herein, the claims still encompass a nucleic acid having at least one cPPT sequence and at least one CTS sequence wherein any other sequences of *pol* is absent (i.e., the claim encompasses a

Art Unit: 1635

sequence wherein the cPPT sequence and CTS sequence are present, but not the sequence between the cPPT and CTS sequences). As such, the rejections under 35 USC 112 first paragraph (indicated above) are appropriate for the reasons indicated herein.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (571) 272-0756. The examiner can normally be reached on M-F (8:00-5:30) with every other Friday off.

Application/Control Number: 09/685,343


Page 9

Art Unit: 1635

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

J. Eric Angell, Ph.D.
Art unit 1635



DAVE T. NGUYEN
PRIMARY EXAMINER